

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS**

IN RE PRADAXA)	MDL No. 2385
(DABIGATRAN ETEXILATE))	3:12-md-02385-DRH-SCW
PRODUCTS LIABILITY)	Judge David R. Herndon
LITIGATION)	

This Document Relates to:

ALL CASES

CASE MANAGEMENT ORDER NUMBER 65

Addressing Motions Challenging Certain Confidentiality Designations

HERNDON, Chief Judge:

I. INTRODUCTION

This matter is before the Court on two motions filed by the Plaintiffs' Steering Committee ("PSC"): (1) motion challenging the confidentiality designations placed on certain deposition testimony by defendants Boehringer Ingelheim International GmbH and Boehringer Ingelheim Pharmaceuticals, Inc. (collectively referred to herein as "BI") (Doc. 463) and (2) motion challenging the confidentiality designations placed on certain deposition exhibits by BI (Doc. 464). BI has responded to each motion (Doc. 472 and Doc. 471). For the reasons discussed herein the Court finds in favor of BI.¹ The motions to remove BI's confidentiality designations are therefore DENIED.

¹ BI has requested oral argument. That request is denied as unnecessary. BI has also requested that the Court refrain from ruling and instead direct the PSC to bring any remaining confidentiality objections in a single motion. That request is also denied.

II. ANALYSIS

A. Applicable Standards

Pursuant to Federal Rule of Civil Procedure 26(c)(1), a court may “for good cause” issue a protective order requiring that “confidential research, development or commercial information” be revealed in a particular way. Fed. R. Civ. P. 26(c)(1)(G). The Court exercised this power by entering Amended CMO 2, which is designed to “protect[] the defendants’ commercially sensitive information while fostering the truth seeking function of the discovery process” (Doc. 176 p. 8). The Court further explained in CMO 56 that to sustain a confidentiality designation under Amended CMO 2, BI must “demonstrate a particular need for protection” and offer “evidence that a clearly defined and serious injury will result” in the absence of the confidentiality protection (Doc. 397 p. 5).

In the instant case, BI bears the burden of establishing that its confidentiality designations are proper.

B. Confidentiality Designations - Deposition Testimony (Doc. 463)

In accord with Amended CMO 2,² the PSC challenges the confidentiality designations that BI has placed on certain deposition testimony. Specifically, the

² Amended CMO 2 allows a party to designate a document confidential or highly confidential. The term “confidential information” is defined as “information, documents, things or data of any type, kind or character that the Producing Party believes in good faith constitutes, reflects, discloses, or contains information subject to protection under Fed. R. Civ. P. 26(c) or other applicable law” (Doc. 208 p. 3). The term “highly confidential information” is defined as “highly sensitive Confidential Information which, if disclosed to a competitor or the general public, could result in substantial business harm by revealing trade secrets, manufacturing processes, proprietary design, drug formulation, drug development, sequencing, chemical stability and characteristics, analytical methods used in manufacturing, quality control processes, CMC information exchanged

PSC challenges three sections of deposition testimony from two BI employees, Dr. Jeffrey Friedman and Dr. Janet Schnee. The PSC contends that the testimony in issue does not contain the type of sensitive and proprietary information that is entitled to the confidentiality protections allowed by Amended CMO 2 and asks the Court to order BI to remove the confidentiality designations it has placed on the same.

BI contends that the disputed confidentiality designations are appropriate for the following reasons:

- The testimony relates to BI's re-examination of the RE-LY trial³
- BI's business, legal, and regulatory strategy for seeking FDA approval, information that would be of considerable value to BI's competitors

After reviewing the disputed confidentiality designations, the Court finds that BI has met its burden of establishing good cause for the same. As to Dr. Schnee's testimony, the disputed excerpts relate to an ongoing scientific investigation by BI. The public release of that information could harm BI's scientific investigation. As to Dr. Friedman's testimony, the disputed excerpts relate to incomplete and/or ongoing scientific investigation. Further, the testimony

with the FDA and not the subject of a patent, source and specifications for drug components and raw materials, manufacturing plans, unpublished patent applications, strategic intellectual property plans, notices of invention, including but not limited to confidential intellectual property and patentable data, information, products or processes" (Doc. 208 p. 3).

³ In CMO 58, the Court concluded that the RE-LY re-examination was an ongoing scientific process and declined "to give plaintiffs a virtual place at the table" during this process (Doc. 425 p. 4). The Court explained that disclosure of details of an incomplete scientific re-examination, whether to the PSC or to the public, "could very well, if not almost guarantee, a stifling of the purpose of the re-examination" (Doc. 425 p. 4). Accordingly, the Court concluded the PSC could not have access to the information from the re-examination until the process was complete (Doc. 425 p. 4).

implicates BI's intellectual property as well as its business, legal, and regulatory strategy.

Accordingly, the motion to de-designate the contested testimony is DENIED.

C. Confidentiality Designations - Certain Deposition Exhibits (Doc. 464).

In accord with Amended CMO 2, the PSC challenges the confidentiality designations that BI has placed twenty-four documents used as exhibits in the depositions of Jutta Heinrich-Nols and Klaus Dugi. BI contends the disputed documents fall within the protection afforded by Amended CMO 2 and Rule 26. Specifically, it asserts the disputed documents contain confidential trade secrets, research and development information, business strategies, and intellectual property, the disclosure of which would result in a serious and particularized financial harm to BI.

The Court has reviewed the disputed documents and BI's assertions with regard to the same. The Court concludes that BI has met its burden with respect to establishing that the designations are appropriate. The disputed documents implicate intellectual property, trade secrets, non-public research and development, and/or business and regulatory strategy. In addition, some of the documents are subject to confidentiality provisions of a collaboration agreement between BI and a third-party. At this time, confidentiality is necessary to protect

the commercial value of BI's relationship with this third-party.

**Accordingly, the motion to de-designate the contested documents is
DENIED.**

SO ORDERED:

 Digitally signed by
David R. Herndon
Date: 2014.04.30
16:24:57 -05'00'

**Chief Judge
United States District Court**

Date: April 30, 2014